HD

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,905	04/24/2001	E. Lauber	VANM190.001A	8920

20995 7590 12/17/2003

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
LAMBERTSON, DAVID A	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/743,905	LAUBER ET AL.	
	Examiner	Art Unit	
	David A. Lambertson	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 02 October 2003.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-26 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-3 and 5-26 is/are rejected.

7)☒ Claim(s) 4 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II (claims 1-26 as they read on SEQ ID NO: 3) in the Amendment filed October 2, 2003 is acknowledged.

Claims 1-26 (as they read on SEQ ID NO: 3) are pending and under consideration in the instant application. The subject matter concerning SEQ ID NO: 1 and 5 has been withdrawn from consideration in all claims as being drawn to non-elected subject matter, and is not examined on the merits.

Information Disclosure Statement

The information disclosure statements filed April 24, 2001 and October 2, 2003 have been considered, and a signed and initialed copy of the form PTO-1449s are attached to this Office Action.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

The full name of each inventor (family name and at least one given name together with any initial) has not been set forth.

Specifically, inventor E. Lauber has made alterations to the residence without initialing those alterations. Additionally, the Oath does not set forth at least one given name for inventor E. Lauber.

Specification

The abstract of the disclosure is objected to because the USPTO no longer accepts the photocopying of Abstracts from International Publications in National Stage Applications. Correction is required. See MPEP § 608.01(b). It would be remedial to supply an Abstract in an amendment, wherein the amendment is not a photocopy of the first page of an international application (e.g., by presenting an amendment wherein the Abstract is re-typed).

The specification is objected to for failing to properly identify amino acid and nucleic acid sequences contained within the specification. Specifically, pages 8-10 list pairs of amino acid and nucleotide sequences that are identified by only a single identifier. It is unclear which sequence (i.e., the amino acid or the nucleotide sequence) corresponds to each identifier; furthermore, the identifier for the other sequence is absent from the sequence. The amendment filed October 2, 2003, while correcting the accuracy of the single identifier, does not remedy the matter. In addition, the amendment indicates a correction on page 11, lines 16-20 that appears to be meant for page 12, lines 16-20 (see page 3 of the response filed October 2, 2003). Although, this objection to the specification does not prohibit the examination of the application at this time, appropriate correction of these issues is required.

Claim Objections

Claims 1, 2, 4, 11, 14-22 and 26 are objected to because of the following informalities:

Claim 1 (and several additional claims) recites an acronym (TGB-3) without first spelling out the acronym. It would be remedial to indicate that "TGB-3" stands for "triple block gene 3" prior to citing "TGB-3" parenthetically in the first claim in which the acronym appears.

Claim 2 (and several additional claims) recites an acronym (BNYVV) without first spelling out the acronym. It would be remedial to indicate what "BNYVV" stands for prior to citing "BNYVV" parenthetically in the first claim in which the acronym appears.

Claims 4, 14-22 and 26 recite non-elected subject matter in the claim. Specifically, these claims recite SEQ ID NO: 1 and 5 in the claim, although these sequences *are not* examined in the instant application because they are non-elected subject matter without traverse. Applicant is required to remove the recitation of these sequences from the claims.

Claim 11 appears to recite a spelling error in that it indicates the use of a "foreigner promoter." Although it is presumed this is meant to read "foreign promoter," formal correction is required on the record.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 5-13 and 23-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims any genetically modified TGB-3 viral sequence identified in an assay designed to uncover TGB-3 viral sequences that inhibit the infection of a virus into a cell. The claims read on a broad genus of TGB-3 mutant viral sequences that must necessarily have the functional ability to inhibit viral infection.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics sufficient to show applicants were in possession of the claimed genus. In the instant case, the specification does not sufficiently describe a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics.

Applicant claims TGB-3 viral sequences that inhibit the infection of a virus into a cell by function only, without any disclosed or known correlation between the elements and their function. There is no indication in the specification as to what types of mutations in a TGB-3 sequence actually leads to the functional ability to prevent viral infection. The specification only provides teachings regarding three specific mutations, SEQ ID NO: 1, 3 and 5, which are suggested to have this functional property. There is no correlation between these sequences that would allow the skilled artisan to envision what other possible mutations would confer this functional property on the TGB-3 sequence; indeed, there is not even an indication in the

specification that any of these three sequences actually has the ability to inhibit viral infection. Thus, the specification does not teach how to envision the claimed genus of genetically modified TGB-3 viral sequences that have the ability to inhibit viral infection. Because the skilled artisan cannot envision a sufficient number of embodiments of the instant invention from the instant specification, the specification does not satisfy the written description requirement for the claimed subject matter.

The prior art does not provide sufficient information on the subject to overcome the deficiencies of the instant specification. There is no description in the prior art that allows one to envision a representative number of TGB-3 mutant sequences to describe the claimed genus of genetically modified TGB-3 sequences having the ability to inhibit viral infection. Thus the skilled artisan cannot rely on the prior art to envision a sufficient number of embodiments of the instant invention to see that the applicant was in possession of the claimed genus.

Neither the specification of the instant application or the prior art teaches a structure-function relationship for a representative number of genetically modified TGB-3 viral sequences that have the ability to inhibit viral infection. As a result, the skilled artisan would not be able to envision the claimed invention by relying on the teachings of the prior art or the instant specification. Therefore applicant has not satisfied the written description requirement to show the skilled artisan that they were in possession of the claimed genus.

Claims 3, 5-13 and 23-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO: 3 (as it relates to the elected subject matter), and the ability to inhibit the infection of a furovirus, does not reasonably provide enablement for

all genetically modified TGB-3 viral sequences and their ability to inhibit the infection of cells by all viruses. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the specification coupled with information known in the art without undue experimentation (*United States v. Telectronics.*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based upon a single factor but rather is a conclusion reached by weighing many factors. These factors were outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988), and the most relevant factors are indicated below:

Nature of the invention. The nature of the invention is: (A) a genetically modified TGB-3 viral sequence having the ability to inhibit the infection of a cell by a virus (claims 3, 5 and 23); and (B) a method of using such a sequence to induce resistance to a virus in a plant cell (claims 6-13, 24 and 25). With regard to the sequence itself, it is important to note that the ability to potentially *identify a sequence* is not commensurate with the ability to *actually make the sequence.*

Scope of the invention. The scope of the invention is very broad with regard to both (A) and (B) as recited above. As it regards (A), this matter is also discussed above with regard to the Written Description requirement. In order to make the sequence, the skilled artisan must be able to envision the sequence. In the instant case, the specification describes three sequences (SEQ ID NO: 1, 3, and 5, of which SEQ ID NO: 3 is the elected subject matter) that prospectively have

the ability to inhibit viral infection (again, there is no actual demonstration for this activity for SEQ ID NO: 3 in the specification). However, there is no structure-function relationship between these sequences such that the skilled artisan would be able to clearly envision (and thus make) the claimed sequences that have the functional ability to inhibit viral infection. In other words, while the skilled artisan can make SEQ ID NO: 1, 3 or 5 (although only SEQ ID NO: 3 is elected and examined in the instant application), the skilled artisan could not make a fourth sequence that has the ability to inhibit viral infection based solely on the structure of the disclosed sequences/the teachings of the instant specification.

As it regards (B), the range of viruses that can be inhibited by SEQ ID NO: 3 is claimed in a very broad sense. It is not clear that this sequence would be able to inhibit the infection of a plant by any virus other than a furovirus, especially by the mechanism proposed in the instant specification (i.e., competition with a wildtype protein for the viral element of replication- see for example page 6, lines 14-22 of the instant specification). Thus, the skilled artisan would not be apprised of how to use such a sequence to inhibit the full scope of viruses, as claimed.

State of the art and Level of skill in the art. The state of the art is silent with regard to making mutations in TGB-3 genes such that the gene has the functional ability to inhibit infection of a plant cell with a furovirus, let alone any virus. There is no demonstration of a structure-function relationship regarding TGB-3 sequences that have the ability to inhibit viral infection. Thus, the skilled artisan could not turn to the prior art to make a mutation in a TGB-3 gene, with the exception of the mutant represented by SEQ ID NO: 3, such that the mutant confers resistance to infection by either a furovirus or any other virus. Similarly, the skilled artisan would not know

how to use SEQ ID NO: 3 to induce resistance to an infection by any virus other than a furovirus, there being no known relationship between TGB-3 sequences and other viruses.

Number of working examples and Guidance provided by applicant. Applicant provides no working examples as it regards the use of any genetically modified TGB-3 viral sequence to increase the resistance of viral infection in a plant. There is not even a working example indicating that SEQ ID NO: 3, when expressed in a plant cell, inhibits the infection of plant cells by a furovirus, let alone any virus. The only guidance the specification provides is the hypothetical assertion that, when SEQ ID NO: 3 is expressed from a replicon in a plant cell, that the susceptibility of the cell to viral infection is reduced.

Unpredictability of the art and Amount of experimentation required. The claimed invention is highly unpredictable over the broad scope in which it is claimed. There is no indication in the prior art on how to mutate a TGB-3 viral sequence such that the mutant obtains the functional ability to reduce the susceptibility of a cell to viral infection. The instant specification does little to overcome this deficiency in the prior art, describing only three particular mutants in the specification (SEQ ID NO: 1, 3 and 5), which are proposed to have this functional property. However, not only is there no indication in the specification of a structure-function relationship for TGB-3 gene mutants that have the ability to confer resistance to viral infection within a plant, there is also no indication that the three mutants have any effect on viral infection. Thus, in order to make and use the instant invention, the skilled artisan would have to perform empirical trial and error experimentation in an unpredictable and undue manner. The skilled artisan would have to make mutants in TGB-3 viral sequences with no guidance from either the prior art or the instant specification, and then test each of these mutants for their ability to inhibit viral infection

in plant cells. The instant claims are simply an invitation for the skilled artisan to experiment in hopes of identifying the claimed sequences that have the functional ability to inhibit viral infection of plants. Because the ability to identify a sequence is not equivalent to the ability to make and use the claimed sequences, the instant claims are not enabled.

In conclusion, the invention is enabled for SEQ ID NO: 3, and its ability to confer resistance to a furovirus in a plant cell. However, the invention is not enabled for *any* genetically modified TGB-3 viral sequence which has the ability to induce resistance to any virus in a plant cell because the skilled artisan could not make or use such a sequence in the claimed manner (i.e., to induce viral resistance in a plant) when armed only with the teachings of the instant specification. That is because the skilled artisan would have to randomly identify other prospective mutant TGB-3 sequences and then test their ability to inhibit viral infection. This is simply an invitation to experiment. As a result, the claimed invention is not enabled across the full scope of which it is claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,2, 6-13, 22, 24 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to recite a positive process step that refers back to the preamble of the claim. In order for the claimed method to be definite in terms of the metes and bounds of the invention, the claim

must recite a method step that provides for the result of the methods as claimed. Without such a step, there is no apparent endpoint to define the metes and bound of the method. It would be remedial to state "thereby identifying mutants in a TGB-3 viral sequence that inhibits infection of a virus into a cell" at the end of the claim.

Claims 6-13, 24 and 25 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to recite a positive process step that refers back to the preamble of the claim. In order for the claimed method to be definite in terms of the metes and bounds of the invention, the claim must recite a method step that provides for the result of the methods as claimed. Without such a step, there is no apparent endpoint to define the metes and bound of the method. It would be remedial to state "thereby inducing resistance to a virus in a plant or plant cell" at the end of the claim.

Claim 22 is indefinite for use of the term "reproducible structure." This term is not defined in the specification, and does not appear to be a term that is commonly used and recognized in the prior art. Therefore, it is unclear what is contained within the meaning of "reproducible structure" in the context of the claims, thus the metes and bounds of the claim are indefinite.

Claim 24 is indefinite because it refers to "the method of claim 5." Because claim 5 is not directed to a method, it is unclear if claim 24 relates to a method, or a vector (the subject matter to which claim 5 applies).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 6-21, 25 and 26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-5, 7-11, 13, 14, 16-20, 23 and 24 (respectively) of US Patent No. 6,297,428 (henceforth the '428 patent).

Although the conflicting claims are not identical in scope, they are not patentably distinct from each other because claims 6-21, 25 and 26 of the instant application are generic claims that are anticipated by the specific claims of the '428 patent. Specifically, claims 6-21, 25 and 26 encompass the subject matter claimed by claims 1, 3-5, 7-11, 13, 14, 16-20, 23 and 24 of the '428 patent, therefore the '428 claims must necessarily anticipate the instant claims. For example, claim 1 of the '428 patent involves a method of inducing resistance to a furovirus in a plant that includes transforming the plant with a nucleic acid corresponding to mutant form of a triple gene block 3 (TGB-3) gene that is operably linked to a regulatory sequence active in a plant cell. Although the scope of the claim is not identical with instant claim 6, the subject

matter is overlapping to the extent that instant claim 6 encompasses claim 1 of the '428 patent. The same argument holds true for each or the remaining claims as set forth above.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the patent. Also, if both patents are issued and the patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding the US Patent No. 6,297,428, then two different assignees would hold a patent to the same claimed invention and thus improperly there would be possible harassment by multiple assignees.

Importantly, there is no showing in the application that the inventions were commonly assigned at the time of invention, although the inventions are currently commonly assigned. The Assignee is required to either (i) name the First Inventor of Conflicting Subject Matter under 102(f) or (g), or (ii) show the inventions were commonly owned at the time of Applicant's invention.

Allowable Subject Matter

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson, Ph.D.
AU 1636

JAMES KETTER
PRIMARY EXAMINER